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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/156,804 09/17/98 KALTENBACH

P 10980096-1

EXAMINER

IM52/0425

AGILENT TECHNOLOGIES  
LEGAL DEPARTMENT, 51U-PD  
INTELLECTUAL PROPERTY ADMINISTRATION  
P.O. BOX 58043  
SANTA CLARA CA 95052-8043

REX, F

ART UNIT

PAPER NUMBER

1743

DATE MAILED:

04/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
**09/156,804**

Applicant(s)  
**Kaltenbach et al.**

Examiner  
**Patricia Kathryn B x**

Group Art Unit  
**1743**



☒ Responsive to communication(s) filed on Feb 17, 2001

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1-12, 25, and 26 is/are pending in the applicat

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-12, 25, and 26 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit:

### **DETAILED ACTION**

1. Applicant's cancellation of claims 13-24 and 27, in Paper No. 11 is acknowledged and has been entered into the record.

#### ***Continued Prosecution Application***

2. The request filed on February 17, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/156,804 is acceptable and a CPA has been established. An action on the CPA follows.

#### ***Claim Rejections - 35 U.S.C. § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1 and 25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant specification does not support the limitation "upon application of a driving force resulting from *simultaneous* operative and modular coupling". Applicant cite page 10, line 14- page 11, line 17 for support of this limitation. However, these pages simply describe a membrane 108 coving the reservoirs 106a which can be punctured by a protrusion arm on the separation unit, which allows the reagents to *flow* from the reservoir unit into the separation unit. There is no mention of the process of supplying liquid

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reagents and analyte to the separation unit upon application of a driving force resulting from *simultaneous* operative and modular coupling.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-12, 25-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, paragraph b, line 1, the limitation "having dimensions compatible with the separation unit" is indefinite. It is not clear as to what Applicant means by "dimensions compatible". How are they compatible? Same deficiency was found in claim 25.

***Claim Rejections - 35 U.S.C. § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

8. Claims 1, 3-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Johnson *et al* (USP 4,806,316).

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Johnson *et al* teach a separation unit 11 having a microchannels 25, in which the analyte can be driven to pass through the microchannel due to the molecular characteristics thereof and wherein the time for the analyte to pass through the microchannel being indicative of the molecular characteristics of the analyte and a prepackaged reservoir unit 29 having one reservoir with dimensions compatible with the separation unit operatively and modularly coupled in fixed alignment via threads 27 on the separation unit, which creates a driving force, e.g. gravity resulting from the simultaneous operative and modular coupling. Moreover, the reservoir unit is used to supply liquid reagents to the separation unit when coupled (column 4 lines 4-57, Figs. 1-9).

9. Claims 1, 3-4 are rejected under 35 U.S.C. 102(e) as being anticipated by Bjornson *et al* (USP 6,103,199).

Bjornson *et al* teach a separation unit 210, 310, 410, 710 having a microchannels (Figs. 5-12), in which the analyte can be driven to pass through the microchannel due to the molecular characteristics thereof and wherein the time for the analyte to pass through the microchannel being indicative of the molecular characteristics of the analyte. Bjornson *et al* further teach a reservoir unit having one or more reservoirs 700 with dimensions compatible with the separation unit operatively and modularly coupled in fixed alignment (Figs. 8-12) to the separation unit to supply reagent and analyte thereto upon application of a driving force resulting from simultaneous operative and modular coupling. The reservoir having prepackaged liquid reagent

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therein before the reservoir unit is coupled to the separation unit (column 26 line 15- column 27, lines 38).

***Claim Rejections - 35 U.S.C. § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 1- 4, 6-7 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swedberg *et al* (USP 5,571,410) in view of Baker *et al* (USP 4,654,127).

Swedberg *et al* teaches a separation unit 2 having a microchannel, in which the analyte can be driven to pass through the microchannel 10 due to the molecular characteristics thereof and wherein the time for the analyte to pass through the microchannel being indicative of the molecular characteristics of the analyte and a reservoir unit having one or more reservoirs having dimensions compatible with the separation unit operatively and modularly coupled in alignment

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to the separation unit to supply liquid reagents thereto (column 29, lines 47-56). Swedberg *et al* do not teach that the reservoirs are prepackaged liquid reagents and analyte therein before the reservoir unit is coupled with the separation unit and upon application of driving force from simultaneous operative and modular coupling. Baker *et al* do teach a separation unit 12 having a microchannel 20, in which the analyte can be driven to pass through the microchannel and a reservoir unit 36 having one or more reservoirs 40, 42 having dimensions compatible with the separation unit operatively and modularly coupled in fixed alignment via tongue 118 and groove 120 structures to the separation unit to supply liquid reagents and analytes thereto upon application of a driving force resulting from simultaneous operative and modular coupling (column 29 lines 47-56), the reservoirs having prepackaged liquid reagents therein before the reservoir unit is coupled to the separation unit. Further, the reservoir unit includes 126, 128 membranes covering the reservoirs confining the prepackaged liquid reagent therein (col. 4, lines 4-48, Figs. 2-8). Note: modularly coupled is defined in the instant application as meaning the apparatus containing various parts or components which can be assembled for use *at the point of use* without extensive calibration or testing. Further, fixed alignment is defined as various parts of the modularly couplable apparatus which are assembled together to form the analytical apparatus, which is clearly taught by Swedberg *et al* do not teach that the reservoirs are prepackaged liquid reagents and analyte therein before the reservoir unit is coupled with the separation unit.

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Accordingly, it would have been obvious to one skilled in the art at the time of the invention to have included in the apparatus of Swedberg *et al* prepackaged liquid reagents and analytes, as taught by Baker *et al*, in order to ensure that the reagents avoid contamination before introduction in the microchannel and eliminates the need for handling of calibrated reagents (col. 2, lines 50-51).

13. Claims 5, 8-9 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swedberg *et al*. (USP 5,571,410) in view of Baker *et al* (USP 4,654,127), as applied to claim 2 above, and in further view of Kambara *et al* (USP 5,968,331).

Swedberg *et al* and Baker *et al* as disclosed above, do not teach an apparatus wherein the membranes are penetrable with a probe, the probe being used for applying a driving force to drive movement of the liquid reagent and analyte from the reservoir through the microchannel. Kambara *et al* do teach a reservoir unit 53 containing a liquid and being penetrable with probes 54, where the probes 54 used for applying a driving force to drive chemicals from the reservoir through the microchannel 15 (column 8 lines 4-40).

Therefore, it would have been obvious to one skilled in the art at the time of the invention to have included in the apparatus of Swedberg *et al* and Baker *et al*, probes to drive liquid into the microchannels, in order to reduce the time and labor needed to introduce the liquids in the microchannels, such as the case when microsyringes are used (column 1 lines 60-63).



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14. Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swedberg *et al.* (USP 5,571,410) and Baker *et al.* (USP 4,654,127) and Kambara *et al.* (USP 5,968,331), as applied to claim 26, and further in view of Kaltenbach *et al.* (USP 5,641,400).

Swedberg *et al.*, Baker *et al.* and Kambara *et al.* as disclosed above, do not teach an apparatus comprising a peltier plate operatively and modularly coupled to the support plate for controlling the temperature thereof. However, Kaltenbach *et al.* do teach peltier plates for coupling to the support plate for controlling the temperature thereof (column 20 lines 37-67 and column 21 lines 1-37, Figures 9A-10B).

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to have included in the apparatus of Swedberg *et al.*, Baker *et al.* and Kambara *et al.*, peltier plates coupled to the support plate, in order to influence many of the physical and chemical parameters involved in separation techniques and decrease the time needed to perform the separation. The temperature can affect the sample stability, buffer viscosity, chemical equilibria, pH and the resulting migration time for a given chemical species (column 3 lines 9-21).

#### ***Response to Arguments***

15. Applicant's arguments filed January 2, 2001 have been fully considered but they are not persuasive. Applicant argues that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into

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account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicant argues that Baker *et al* do not teach operative and modular coupling, the cylindrical reservoir is mounted within a sleeve of an analytical unit and then rotated. Examiner believes that Baker *et al* do teach an apparatus which contains various parts or components which can be assembled for use at the point of use without extensive calibration or testing as defined in the instant specification. Therefore, the fact that Baker *et al* requires a rotation step is not germane to the issue since such a step has not been excluded from the claims and meets the defined requirements of modular coupling as defined in the specification.

Applicant argues that Baker *et al* do not teach a reservoir which is in fixed alignment with the separation unit because the reservoir unit is rotatable, not fixed. The instant specification, as pointed out by Applicant, has defined fixed alignment as meaning two pieces that are held in a dimensionally fixed relationship in direct contact or through one or more interposing pieces between the operatively coupled or operatively connected pieces. On page 18, lines 6-7, the fixed alignment is further defined as various parts of the modularly couplable apparatus of the present invention assembled together to form the analytical apparatus. Preferable there are notches, *tongue and groove structures and the like in various part to facilitate the efficient alignment for*

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*coupling*. Such tongue 118 and groove 120 structures for fixing the separation unit and reservoir unit are clearly taught in Baker *et al*, see Figs. 5A-5C.


***Conclusion***


16. No claims allowed.

17. References: Murphy *et al*. is cited as art of interest for the teaching of an prepackaged reservoir unit coupled to a container.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Bex whose telephone number is (703) 306-5697.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0651.

  
P. Kathryn Bex  
Patent Examiner  
Art Unit 1743  
April 23, 2001

  
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